

AMENDMENTS TO THE DRAWINGS

Figures 3 and 4 are added.

Attachment: New Sheet(s)

REMARKS

Summary Of The Office Action & Formalities

Status of Claims

Claims 1-22 are all the claims pending in the application. By this Amendment, Applicant is amending claims 20 and 21. No new matter is added.

Claim to Foreign Priority

Applicant thanks the Examiner for acknowledging the claim to foreign priority and for confirming that the certified copy of the priority document was received.

Drawings

The drawings are objected to under 37 CFR 1.83(a). The drawings must show every feature of the invention specified in the claims. Therefore, “a plurality of blisters” in line 2 of claim 1, “openings” in line 4 of claim 1 and “a dry-powder inhaler” in line 1 of claim 20, must be shown or the feature(s) canceled from the claim(s). (Office Action at page 2.)

Applicant is adding new Figs. 3 and 4 to address this objection.

Claim Rejections - § 112

Claims 21 and 20 are rejected under 35 U.S.C. § 112, second paragraph, for the reason set forth at page 3 of the Office Action.

Applicant is amending the claims to overcome this rejection.

Art Rejections

1. Claims 1-4, 7-9, 11, 13 and 20-22 are rejected under 35 U.S.C. § 103(a) as being unpatentable over Ekelius et al. (US 6,637,431 (Ekelius)) in view of Razeti (US 2003/0108714).

2. Claim 1 is rejected under 35 U.S.C. § 103(a) as being unpatentable over Ekelius in view of Razeti and further in view of Fuller et al. (US 2002/0008046 (Fuller)).

3. Claim 14 is rejected under 35 U.S.C. § 103(a) as being unpatentable over Ekelius in view of Razeti and further in view of Lippert (US 4,938,414).

Applicant respectfully traverses.

Claim Rejections - 35 U.S.C. § 103

1. *Claims 1-4, 7-9, 11, 13 And 20-22 Over Ekelius et al. (US 6,637,431) In View Of Razeti (US 2003/0108714).*

In rejecting claims 1-4, 7-9, 11, 13 and 20-22 over Ekelius et al. (US 6,637,431) in view of Razeti (US 2003/0108714), the grounds of rejection state:

In reference to Claim 1

Ekelius discloses a blister strip (12) for use in a fluid or powder inhaler, and including a plurality of blisters (13), each formed by a reservoir (created by 19) including an opening (at the top of 19, see Figure 10) that is sealed in leaktight manner by a tearable layer (20) and a cavity layer (18) that is provided with cavities (19) forming the blister walls.

Ekelius discloses the claimed invention as discussed above with the exception of the following claimed limitations that are taught by Razeti: a base layer (19) that is provided with openings (23, Figure 5) forming the openings of the blisters, and said tearable layer (20, of Ekelius see above) comprising a first tearable-layer portion (21) that is disposed between said base layer (19) and said cavity layer (18 of Ekelius), and a second tearable-layer portion (22) that is disposed on the opposite side of said base layer, said first and second tearable-layer portions being connected together at each opening of the base portion (see figures 4 and 5, where the first and second tearable layers (21 and 22 are connected at 23 and 24).

It would have been obvious to one of ordinary skill in the art at the time of the invention to modify Ekelius in view of Razeti so that the tearable layer in Ekelius is modified with features of Ekelius, in order to make the container opening operations convenient for users, as taught by Razeti (column 1, paragraphs 0011).

* * *

In reference to Claim 21

Ekelius discloses a blister strip (12) for use in a fluid or powder inhaler, comprising: a blister (13) formed by a reservoir (created by 19) comprising a blister opening (at the top of 19, see Figure 10); a first tearable layer (20) sealing the blister opening (see Figure 10).

Ekelius teaches the claimed invention as discussed above with the exception of the following claimed limitations that are taught by Razeti: a base layer (19) above the first tearable layer (the first tearable layer 20 of Ekelius is replaced with 21 of Razeti) and comprising a base layer opening (23) corresponding to the blister opening (container opening 24); a second tearable layer (22) above the base layer and connected to the first tearable by a material connection (see Figure 5, 21 and 22) passing through the base layer opening so that, upon lifting the second tearable layer (22), an edge of the base layer opening tears the material connection formed between the first tearable layer and the second tearable (see figure 5 where lifting 22 tears the material connection formed at the opening), thereby unsealing the blister opening (see Figure 5).

It would have been obvious to one of ordinary skill in the art at the time of the invention to modify Ekelius in view of Razeti so that the tearable layer in Ekelius is modified with features of Ekelius, in order to make the container opening operations convenient for users, as taught by Razeti (column 1, paragraphs 0011).

Office Action at pages 3-4 and 7-8 (emphasis added)

In order to find a claim obvious, the Examiner must articulate convincing rationale for why one skilled in the art would have carried out the asserted modification. Indeed, the Supreme Court in *KSR v. Teleflex* left undisturbed the requirement that the Examiner must present “a convincing line of reasoning supporting a rejection.” MPEP § 2144. Furthermore, “rejections on obviousness grounds cannot be sustained by mere conclusory statements; instead, there must be

some articulated reasoning with some rational underpinning to support the legal conclusion of obviousness.” *KSR Int’l Co. v. Teleflex, Inc.*, 550 U.S. 398, 418 (2007).

For at least the reasons discussed below, the grounds of rejection have not adequately satisfied this showing required by the Supreme Court in *KSR*.

As a preliminary matter, Razeti (US20030108714), upon which the Examiner heavily relies for much of the claimed features, is non analogous prior art.

To rely on a reference under 35 U.S.C. § 103, it must be analogous prior art. As set forth in the Manual of Patent Examining Procedure (“MPEP”), “[t]he examiner must determine what is ‘analogous prior art’ for the purpose of analyzing the obviousness of the subject matter at issue. ‘Under the correct analysis, any need or problem known in the field of endeavor at the time of the invention and addressed by the patent [or application at issue] can provide a reason for combining the elements in the manner claimed.’” MPEP Section 2141.01 (citing *KSR Int’l Co. v. Teleflex, Inc.* As explained in the MPEP, the reference must have ***logically commended itself to an inventor's attention in considering his or her invention as a whole. Id.***

Razeti is not such a reference that would have logically commended itself to an inventor developing a blister strip for a fluid or powder inhaler.

Indeed, Razeti discloses a peel-off lid for a ***food container***. The person skilled in the art, considering an improvement for the blister strip of Ekelius would not have looked to Razeti. There is no logical rationale for doing so and certainly not one provided in any of the cited documents for combining Ekelius with Razeti.

An object of the claimed subject matter is to improve the blister strips in inhalers in order to guarantee dispensing of the entire dose and to allow breath-actuation (*see, e.g., p. 2, ll. 7-24*). Neither this nor any other technical problem with the blister packs of Ekelius is mentioned or

solved by Razeti, and thus is further evidence why one skilled in the art would have had no reason to consider Razeti.

Moreover, the food containers disclosed in Razeti are *individual* containers, not a strip of blisters and are intended to be *manually* opened.

Indeed, the rationale provided in the grounds of rejection – “in order to make the container opening operations convenient for users” – is not supported by either applied document, including Razeti. In particular, nowhere does Razeti indicate that the sheet for peel off lids for food containers that are manually peeled off is in any way applicable to blister strips that are used in inhalers such as the one disclosed in Ekelius et al. Furthermore, the grounds of rejection do not explain *how* the lid for containers that are peeled off as disclosed in Razeti could be adapted for use in the particular inhaler mechanism of Ekelius. The Supreme Court was very clear that “rejections on obviousness cannot be sustained by mere conclusory statements.” *KSR Int'l Co.*, 550 U.S. at 418. *See also* MPEP Section 2142.

In view of at least the foregoing differences, the Examiner is requested to reconsider and withdraw the rejection of claims 1 and 21 and claims dependent therefrom.

Furthermore, regarding claim 22, contrary to the grounds of rejection, in Fig. 5 of Razeti, elements 21 and 22 are clearly *two pieces* bonded together (note the different cross-hatching), and thus cannot be a *one-piece* construction as recited in the claim.

Conclusion

In view of the above, reconsideration and allowance of this application are now believed to be in order, and such actions are hereby solicited. If any points remain in issue which the Examiner feels may be best resolved through a personal or telephone interview, the Examiner is kindly requested to contact the undersigned at the telephone number listed below.

The USPTO is directed and authorized to charge all required fees, except for the Issue Fee and the Publication Fee, to Deposit Account No. 19-4880. Please also credit any overpayments to said Deposit Account.

Respectfully submitted,



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